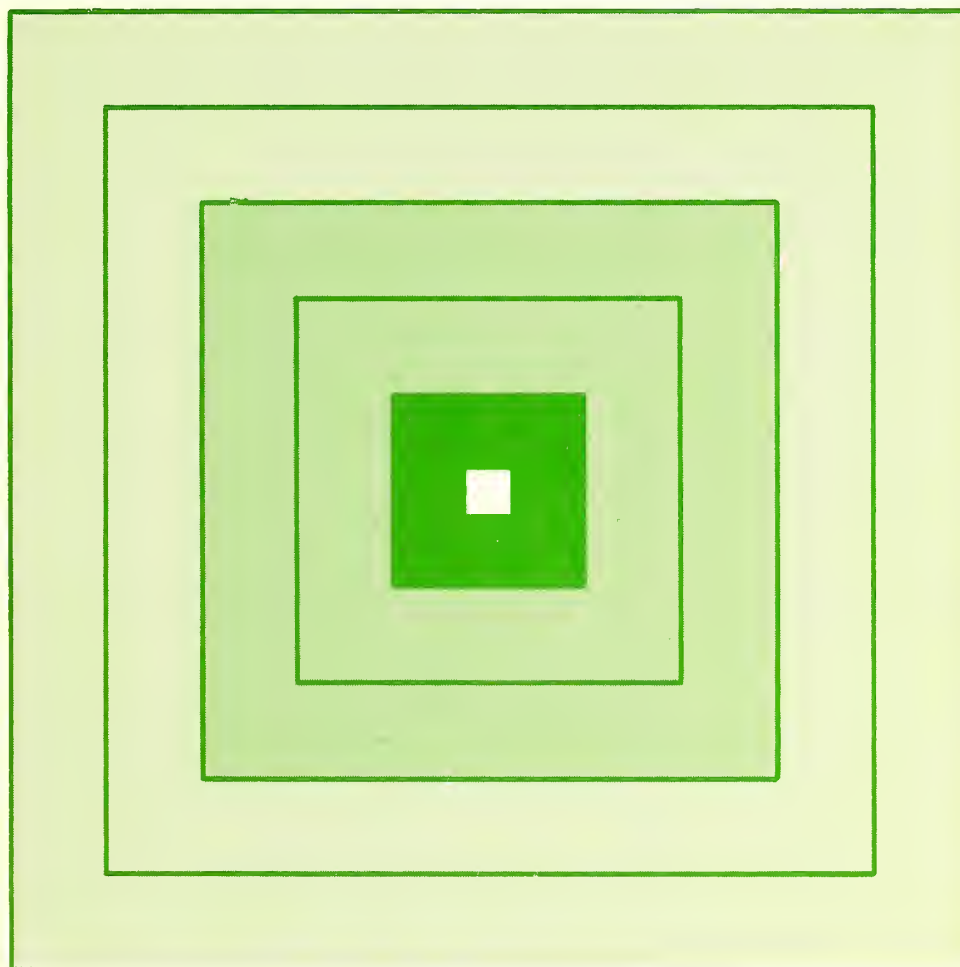


The Acquisition and Maintenance of Medical Equipment



U.S. DEPARTMENT OF COMMERCE
Domestic and International Business Administration
Bureau of Domestic Commerce

The Acquisition and Maintenance of Medical Equipment



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FOREWORD

The growing demand of people throughout the world for more and better health care greatly enlarges the role of medical equipment in providing health services more effectively. The seriousness of the consequences that may arise from the use of defective equipment, including injury or death and malpractice litigation, makes it incumbent upon both manufacturers and users of medical equipment to ensure high quality equipment that is properly made and maintained for safe, effective and reliable operation. In addition, selection of the best available equipment often saves time and money as a result of lower frequency of breakdowns and smaller expenditures for parts and service.

This study reviews some basic considerations relative to selecting, acquiring and maintaining medical equipment for optimum performance. The experiences of a number of hospital equipment specialists regarding maintenance practices and inadequacies are reviewed, as well as the warranties and maintenance services available from manufacturers.

Hopefully, this information will assist physicians, nurses, hospital administrators, equipment manufacturers, and managers of medical equipment maintenance programs in delivering improved service at lower costs. Raising the level of productivity in the delivery of health care services is a goal of vital social and economic importance.

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SUMMARY

U.S. national health care expenditures have grown from \$12 billion in 1950 to an estimated \$104 billion in 1974 increasing at an average annual rate of 9.4 percent. As a percentage of the Gross National Product, the national outlay for health care has increased from 4.6 percent in 1950 to a level of 7.7 percent in 1974.

Nearly 2,000 establishments are involved in manufacturing the products used in providing health services; and the value of shipments for these establishments was reported at \$3.3 billion in 1972. The market value of medical electronic equipment, which comprises a growing part of all medical equipment, was estimated at \$901 million in 1974. The world market for this equipment is growing at an even faster rate than the U.S. market.

The number, variety, and complexity of electro-medical devices is steadily increasing, as is the frequency and degree of direct interface between patient and equipment. As these products assume a more important role in providing health care, a moral as well as a legal obligation is imposed on physicians, nurses, hospital managers and manufacturers with respect to establishing safe and effective procedures for the use, maintenance and repair of medical equipment.

In 1972, the American Hospital Association queried a number of hospital equipment specialists and found that equipment maintenance in hospitals was largely inadequate because: manufacturers had not fully provided for post-sale service and maintenance; users had not accepted responsibility for ensuring adequate maintenance; and both users and manufacturers lacked knowledge of detailed procedures for establishing adequate programs. The findings further indicated that in general, only those hospitals with more than 500 beds provided the necessary maintenance staff and facilities. Although considerable progress has been made in the last few years, it is believed that many of the hospitals with fewer than 300 beds have not yet established adequate maintenance programs. Since over 81 percent of the 7,000 hospitals in the U.S. have fewer than 300 beds, it appears that a large majority of all hospitals could benefit from improved maintenance practices.

It is most important for hospital administrators to evaluate the various options for equipment acquisition and maintenance before deciding on an internal, external, or composite program. Medical equipment manufacturers will find it increasingly necessary to provide spare parts, technical information, training

in use and repair, and other post-sale services to their customers, and to build increased reliability, accuracy and safety into their products.

When new acquisitions of medical equipment are planned, a pre-purchase evaluation should be made to determine the best available equipment. In addition to direct purchase, there is the alternative of leasing or renting medical equipment which requires a much smaller initial cash outlay for equipment and lowers taxes since lease and rental charges are operating expenses.

A brief description of programs that provide maintenance for medical equipment is as follows. An internal program provides a resident maintenance staff for routine and emergency repairs, preventive maintenance, calibration and training of personnel in the use and care of equipment. A modification of this type of program is sharing specialized manpower among several health facilities.

An external maintenance plan utilizes contract service from an equipment manufacturer or an independent service firm for selected equipment maintenance at specified prices. Contracts should precisely spell out the maintenance services to be performed and related costs. Service based on direct billing for parts and labor is also available.

Another program option is a combination of both internal and external maintenance services. This program would be based on an economic evaluation of the costs of hiring additional resident maintenance personnel versus obtaining a maintenance contract for selected critical equipment. Other medical equipment would remain under the care of the internal staff.

From among the above alternatives, it remains for the institution management to select the most economical and effective program that protects the well-being of both patients and staff and also provides for optimum medical equipment service.

Today's modern health care, based increasingly upon the use of sophisticated equipment for the diagnosis of disease, therapeutic procedures, and monitoring of the critically ill, makes maintenance and repair of medical instrumentation a vital necessity. Medical institutions and manufacturers must each recognize the importance and accept mutual responsibility for establishing an effective service structure.

I. OVERVIEW

The Market for Medical Equipment

National health care expenditures have increased rapidly since World War II. Social Security Administration statistics show that U.S. expenditures for health care rose from \$12 billion in 1950 to \$86 billion in 1972, and an estimated \$104 billion in 1974. This is an average annual increase from 1950 to 1974 of 9.4 percent. Even more significantly the national health care outlay, as a percent of Gross National Product, has increased steadily over the years, from 4.6 percent in 1950 to a level of 7.7 percent in 1974.

The combined value of shipments for the major industries producing health care goods was reported in the 1972 Census of Manufactures at \$3.3 billion (3.8 percent of annual health care expenditures). These industries, by Standard Industrial Classification, are:

SIC 3693 - X-Ray Apparatus and Electromedical Equipment

SIC 3841 - Surgical and Medical Instruments and Apparatus

SIC 3842 - Orthopedic, Prosthetic, and Surgical Appliances and Supplies

SIC 3843 - Dental Equipment and Supplies

In each of the above industries, the eight largest firms produced over 53 percent of the value of product shipments for the industry. Nearly 2000 establishments are involved in manufacturing health care products, and about seventy percent of them employ fewer than 20 employees.

A breakdown for medical electronic equipment that comprises a growing part of all medical equipment is as follows:

	<u>Market Value</u> <u>Millions of Dollars</u>		
	<u>1973</u>	<u>1974</u>	<u>73-74</u> <u>% Chg</u>
Diagnostic equipment	\$513.6	\$625.6	22%
Prosthetic equipment	115.3	131.7	14
Therapeutic equipment	45.1	51.5	14
Surgical support equipment	15.3	17.4	14
Patient monitoring systems	<u>64.0</u>	<u>75.0</u>	<u>17</u>
Total	\$753.3	\$901.2	20%

Source: Electronics, McGraw-Hill Publication, Jan. 9, 1975

Markets for medical products include government and private hospitals, clinics, laboratories, sanitariums, nursing homes, medical schools, medical research institutions, public health delivery organizations, industrial medical facilities, pharmaceutical firms, and individual physicians.

The world market for medical equipment is becoming more important as foreign countries raise their health system standards; and the realignment of currencies has helped U.S. manufacturers gain a more favorable competitive position in international trade. A 1973 Global Market Survey by the Department of Commerce projects foreign market growth during the 1970's at about 15 percent annually which is slightly higher than that projected for the U.S. The survey indicated that products having the greatest foreign marketability were automatic blood chemistry analyzers, patient monitoring systems, portable infant incubators, kidney dialysis machines, nebulizers, resuscitation equipment, and intermittent positive pressure breathing equipment. Successful international marketing of medical equipment depends heavily upon publishing technical manuals for equipment operation and maintenance in the native language of the buyer, and providing local servicing and parts availability.

The Need for Responsible Maintenance Programs

Increased frequency and degree of direct interface between patient and equipment has brought new emphasis to the need for maintenance programs. A patient entering a hospital has a high probability of being exposed to or connected to one or more of the following items of medical equipment:

- Patient Monitor
- Heart Pacemaker
- Respirator
- Electrocardiograph (ECG)
- Electroencephalograph (EEG)
- High Voltage Radiotherapy Equipment
- X-ray Equipment
- Defibrillator
- Anesthesia Machine
- Heart Pump
- Dialysis Machine
- Electro-cauterizer
- Suction Pump
- Electric Bed
- Hyperthermia Apparatus
- Heart-Lung Machine

The number, variety, and complexity of electro-medical devices is steadily growing, and as these products assume a more important role in providing health care, a moral as well as a legal obligation is imposed on physicians, nurses, hospital managers and manufacturers with respect to establishing effective procedures for the use, routine maintenance and emergency repair of this equipment.

In 1972, the American Hospital Association queried a number of hospital equipment specialists to determine current maintenance practices (Appendix A). While the problem of inadequate equipment maintenance has been addressed by many hospitals and manufacturers, and by some government and private institutions, it is believed that substantial numbers of hospitals and manufacturers may benefit from this data. The results showed that equipment maintenance was considered to be a problem by over 90% of the specialists, and resulted from the existence (in varying degrees) of the following conditions:

- 1) Equipment manufacturers had not fully recognized the importance of providing post-sale service and maintenance;
- 2) Users had not accepted responsibility for ensuring adequate equipment maintenance; and
- 3) Both users and manufacturers lacked knowledge of detailed procedures for establishing adequate equipment maintenance systems.

Correction of these conditions could enhance the ability of the user to effectively operate and maintain sophisticated medical equipment systems in the hospital environment; increase manufacturer's sales; stimulate development of new and improved products; reduce user costs in maintaining equipment; and reduce the possibility of patient discomfort, injury or death, and liability proceedings.

According to these hospital equipment specialists, diagnostic equipment receives the most frequent use; therapeutic equipment ranks second; laboratory equipment, third; and patient monitoring equipment, fourth. (Appendix B)

The findings further indicated that diagnostic equipment needed most frequent repair, followed by patient monitoring equipment and therapeutic equipment, while the frequency of repair for laboratory equipment was considerably less.

An internal maintenance staff and a spare parts inventory for medical equipment was considered less important for hospitals with fewer than 500 beds than for hospitals with more than 500 beds. Hospitals with more than 500 beds relied less on warranties, while hospitals with fewer than 500 beds depended more heavily on manufacturers' warranties. Warranties and services offered by manufacturers were viewed as inadequate by about half of the participants. The inadequacies cited included limited time and parts coverage of warranties, poor workmanship by inadequately trained servicing personnel; and lengthy repair times.

Although much progress has been made since 1972, recent discussions with professionals in the biomedical field indicate that maintenance of medical equipment remains inadequate and must be more fully recognized as an obligation by both user and manufacturer. Many larger hospitals have recognized the importance of equipment maintenance and now provide a staff of biomedical technicians and engineers, maintenance facilities, and an inventory of spare parts for the equipment. However, the smaller hospitals have generally not yet reached this stage of recognition and few make provision for comprehensive maintenance programs in their planning or fiscal budgeting.

Data from the American Hospital Association show that there were more than 7000 hospitals in the U.S. in 1973. Of these, 81 percent had fewer than 300 beds. The breakdown, according to number of beds, is as follows:

<u>Number of Beds</u>	<u>Hospitals</u>	<u>Percent</u>
1- 99	3,557	50
100-299	2,210	31
300-499	715	10
500- up	<u>641</u>	<u>9</u>
	7,123	100

Even if it is assumed that hospitals with more than 300 beds have adequate maintenance programs, a large majority of all hospitals can still benefit from improved maintenance programs.

The importance of medical equipment maintenance also received recognition at the International Workshop on Bio-medical Equipment Maintenance held in Yugoslavia in April of 1972. The Workshop was sponsored by the U.S. National Science Foundation in cooperation with the Yugoslav Federal Administration for International Scientific, Educational, Cultural, and Technical Cooperation, and was coordinated by the American Institute of Biological Sciences. It was concluded that, in most foreign countries, equipment operation and maintenance can be complicated by a scarcity of spare parts and service personnel. When possible, installation by the manufacturer is desirable to serve as a check on the presence of all parts and satisfactory initial operation, and provide basic training in equipment use and maintenance. When a breakdown occurs, several months may pass before the equipment is again in operation, especially if it must be returned to the manufacturer for repair.

Selection and Acquisition of Medical Equipment

When acquisition of new medical equipment is planned, a critical evaluation should be made of equipment on the market and the expected use. Selection of the best available equipment can save time and money as a result of the shorter time required to train operating personnel and activate equipment, lower frequency of breakdowns and accompanying inconveniences, shorter intervals of inactivity while equipment is being repaired, smaller expenditures for parts and servicing work, and fewer preventive maintenance requirements.^{1/}

In equipment selection, specific attention should be given to facilities needed for installation and use. This may include the availability of gas, water, air conditioning, and electricity. In addition, consideration should be given to proper floor planning for optimum equipment use and maintenance, location of support facilities (e.g. film processing units, remote controls, dressing rooms, etc.), and special requirements such as radiation shielding.

^{1/} The Emergency Care Research Institute in Philadelphia, Pa., a non-profit agency, has a monthly publication, Health Devices, which has evaluated many items of hospital equipment over the past five years.

The post-sale services provided by manufacturers should also be compared. Such services include warranty policies, service representatives to install equipment and train hospital operating personnel, operation and maintenance manuals and schematics, and the availability of prompt repair service and spare parts. Other separate services may be offered by the company, such as post-warranty maintenance contracts and meetings and seminars for training personnel in the latest techniques and uses of the equipment.

Careful attention should be given to special requirements such as calibration and standardization since few hospitals have adequate staff to provide these services. Compatibility of new equipment with existing equipment is important both for safety and for ease of integration into existing diagnostic, therapeutic, or patient monitoring systems. The hospital administrator may find that standardization of power sources, power connectors and other hardware leads to overall economy of operation and a higher degree of safety for the patient despite the higher initial cost.

Currently, an absence of government and industry standards has resulted in a variety of incompatible equipment connectors and devices that present potential health hazards. However, a number of professional and industry associations, for example, the Association for the Advancement of Medical Instrumentation (AAMI), the American National Standards Institute (ANSI), and the National Fire Protection Association (NFPA), have prepared safety standards and are attempting to draw up further guidelines for establishing safety and performance standards. The Federal Government, through the Food and Drug Administration and Occupational Safety and Health Administration, has undertaken the task of deriving and enforcing standards. The Medical Device Amendments of 1975, pending in the 94th Congress would, if enacted, have a definite impact on the design and maintenance of medical equipment by requiring pre-market testing and certification of certain classes of medical equipment and the establishment of standards for others.

All of the above factors have a direct bearing on the total costs that the hospital may incur. Providing proper maintenance of medical equipment is very important in estimating and comparing the "life cycle cost"^{1/} of specific products. This "cost" should include purchase price, cost of energy used in operation, cost of maintenance and repair, and the disposal cost.

^{1/} For a discussion on the concept of "life cycle cost," see, The Productivity of Servicing Consumer Durable Products, Massachusetts Institute of Technology, 1974.

Careful consideration of all life cycle costs will be useful to hospital administrators in determining the best equipment for their purposes. What appears to be the most expensive instrument in the beginning may prove to be less costly in the long run.

In addition to direct purchase, the possibility of leasing or renting necessary equipment should also be considered. The advantages would be a minimum initial outlay of capital and the ability to charge leasing costs to operating expenses for direct tax benefit. Lessors should be selected carefully to ensure reliable equipment and prompt service. Many hospitals and laboratories are increasing their use of leased equipment to gain quick availability and to relieve situations where cash shortages make purchase infeasible. Most of the major health-care equipment manufacturers have lease-agreements available financed directly by the manufacturer or by a bank or other financial institution. There are also independent leasing companies which specialize in health-care equipment.

The decision whether to lease or buy depends upon the situation existing within the institution, and analysis of comparable breakeven costs between lease cost, ownership cost, and the percentage of time the equipment will be productively employed over its useful life. The cost of leasing is usually limited to the monthly fee, whereas ownership costs include maintenance, calibration, depreciation, property tax, and storage, as well as the cost of capital tied up in the equipment.

A recent study^{1/} estimated that the value of new medical equipment leased by the health-care industry approached \$392 million in 1973, and diagnostic, therapeutic, and other biomedical equipment accounted for 40 percent of health-care leasing market. This study estimated that leasing of medical equipment would approach \$1.1 billion by 1975.

^{1/} Health Care Leasing, June 1974, Frost and Sullivan, Inc.

II. MAINTENANCE PROGRAM OPTIONS

Internal and Contracted Services

The goal of an effective equipment maintenance program is to provide an organized maintenance capability and assure optimum availability and functioning of all medical equipment. The ideal medical equipment maintenance program probably consists of a combination of both internal and contracted services. A manager should be selected to be directly responsible for the supervision of all internal and contracted maintenance functions including preventive maintenance. In recent years there has been increased use of biomedical engineers and clinical engineers for this purpose. In addition, the manager should assist in training staff members in the proper use of equipment, and provide expertise in the selection of medical equipment. An internal capacity for installing and maintaining equipment usually increases the overall time that equipment is available for use, and effectively extends warranty coverage under actual usage conditions by hastening installation. Even when the manufacturer installs the medical equipment, internal medical maintenance personnel should be present and a joint pre-acceptance test should be carried out.

An alternative way to provide for maintenance of medical equipment, or to supplement an internal program, is to purchase a maintenance service contract from the manufacturer or from an independent agency. This approach is indicated when internal staff with special skills are not available to perform the necessary work. In addition, service can be obtained on a direct time and materials basis. Response time for external service may be slower than for internal service depending upon distance and other factors.

Contracts for maintenance services should specify in detail the equipment involved, whether labor and parts are included, the maintenance procedure to be utilized, and the frequency of servicing. When possible, a hospital maintenance staff member should accompany the contractor during repair or maintenance visits to assure that all procedures specified in the contract are completed.

Care must be exercised when considering outside maintenance contracts because costs and services can vary widely. Some agreements provide for all-inclusive labor and parts maintenance at a fixed fee; some are based on fixed fee plus parts and emergency travel; some are based on fixed fee plus parts and overtime; and still others provide for fixed fee plus hourly rate and cost of parts. The objective is to obtain a qualified contractor who will fulfill maintenance needs and satisfy hospital management. The lowest bid may not always be best if compromises in qualifications have to be made.

Sharing maintenance services is another option receiving increased attention whereby several hospitals utilize a single organization for repair, calibration, preventive maintenance, pre-purchase evaluation, and staff training. Such organizations are often headed by a professional certified as a clinical engineer with a staff of biomedical technicians and repairmen. ^{1/}

Manufacturers' Maintenance Policies

Most medical equipment manufacturers provide warranties and maintenance services as an extension of their product. While warranties were originally conceived as a marketing device, the high cost of fulfilling warranties has prompted design improvements to increase reliability and make servicing easier. Usually included in the basic package are a warranty for one year covering parts and labor, delivery and installation, training in equipment operation and maintenance, operation manual, maintenance manual, equipment schematic, and availability of spare parts and post-warranty service. However, separate charges may be made for some of these items.

The above services vary in detail with individual manufacturing companies, and coverage within a company may vary for different types of equipment. In general, medical equipment manufacturers have found that at the beginning of the warranty period, 40 to 50 percent of the calls are related to operator type errors rather than equipment malfunctions.

It is important to recognize that nurses are the primary users of medical equipment and many of them apparently feel incompletely trained in equipment operation. Tentative results from a survey being conducted to determine the level of nursing competence on 30 common equipment items reveals that one-fifth of the nurses studied felt that their knowledge of

^{1/} Hospitals, May 16, 1975, p. 80.

electric beds was either poor or incomplete; one-fourth felt the same way about defibrillators and electrocardiogram monitors; and one-third felt that their knowledge of respirators was inadequate. Training efforts that attempt to teach too much electronics have not been successful, but programs that stress proper use of specific equipment on a step-by-step approach have resulted in a drastic reduction in initial service calls due to operator error.^{1/}

Increased use of modular electronic elements in medical equipment will make it possible for fewer types of replacement parts to be stocked for repair and service compared with the many individual components now required. Equipment designed around modular electronic elements can usually be diagnosed, repaired, and returned to proper operating condition more quickly than equipment of traditional design. Even though a single component costs less than a modular element consisting of many components, the labor required to isolate and replace one faulty component and the longer "down-time" involved makes equipment designed around modular elements well worth consideration. However, a larger investment in inventory will be required by the manufacturer as well as more sophisticated testing equipment by the maintenance staff.

Since the hospital specialists contacted in the AHA query indicated that items of equipment needing frequent repairs included electrocardiographs and patient monitors, 1973 equipment manufacturers' data (Appendix C) was examined to reveal variances in post-sales services for these items.

Electrocardiographs (ECG) are standard diagnostic instruments, and sales in the U.S. were about \$17.6 million in 1973 and are forecast at \$24 million for 1977 growing at an average annual rate of 8 percent. Appendix C identifies fifty ECG manufacturers and forty-six of them provide one year warranties covering parts and service costs. The other four companies vary. One provides no warranty, one provides three months, one six months, and one thirty-six months warranty coverage. While most warranties begin with the date of shipment, some may begin with the delivery date of the equipment.

^{1/} Ibid., p. 79.

Thirty-seven of the ECG manufacturers have service organizations and service contracts are available from thirty-six of them. Service charges average about \$25 to \$30 per hour, plus cost of parts. Some manufacturers begin their service charge when the technician leaves the company premises or the previous repair site; others begin when the technician reaches the repair site; and still others begin when the technician reaches the repair site but include a surcharge to cover travel costs. Service contracts also vary in cost according to the number of instruments that have to be serviced, the age of the equipment, the frequency of use of equipment, and the frequency of preventive maintenance calls.

Spare parts are usually available from the factory and at selected field locations. Manufacturers state that most parts can be obtained locally within 24 to 48 hours; but parts ordered from the factory may take a week or more. Service technicians of some companies carry a supply of the more commonly used spare parts.

In addition ECG manufacturers provide three types of training: formal training given at the manufacturing facility or school on equipment functions, operation, and maintenance; informal training given on operation and maintenance of equipment at time of installation; and to a lesser extent, training by service technicians imparted while adjusting or repairing equipment. Manufacturers also furnish operation and maintenance manuals and schematics for the equipment, usually at extra cost.

Patient monitors are relatively new systems of electronic devices for automatically measuring and recording one or more physiological variables and responses of a patient including heart rate, pulse rate, blood pressure, blood gas, respiration rate, and temperature. The monitoring units may be utilized with one or more beds, and the observation may be continually or intermittently relayed to the nursing station or to the basic monitoring station. 1973 sales of patient monitoring equipment in the U.S. were approximately \$50 million and are forecast at \$97 million for 1977, reflecting an average annual growth rate of 18 percent.

Appendix C identifies 85 manufacturers of patient monitoring equipment. Most manufacturers provide a one year warranty covering parts and service, but a few provide coverage for only 3 to 6 months. Some warranties are dependent upon proper

maintenance being carried out at stated intervals by company representatives or hospital personnel for continued validity. Fifty-eight of these manufacturers have service organizations.

Service contracts are available from fifty-two of the manufacturers. Costs vary depending on the number of instruments to be serviced, the frequency of preventive maintenance servicing, the frequency of use of the equipment, and whether the equipment is to be serviced during regular hours or on a 24-hour emergency basis. Hourly service charges average about \$25 to \$30 per hour, plus cost of parts. The hourly cost also varies as to its onset, depending on the policy of the manufacturer.

Inventories of spare parts are maintained at service centers and factories, and parts can usually be obtained in 24 to 48 hours. Many manufacturers enclose a replacement parts catalog with the equipment, and a few suggest parts to be stocked as replacement items.

Manufacturers provide various types of training such as on-the-job training given at time of installation of the equipment, training at a company's training school or facility, or seminars at the user's facility utilizing instructional video tapes and technical information systems. Operation manuals, maintenance manuals, and equipment schematics are usually available at extra cost.

III. ESTABLISHING A MEDICAL MAINTENANCE PROGRAM

Maintenance Facility

An internal shop facility should provide for administrative details, space and tools for maintenance and repair of equipment, and an inventory of spare parts, even when part of the maintenance is performed by contracted services. The facility should be located reasonably close to the principal users of the service such as units for intensive care, clinical physiology, diagnostic examination, inhalation therapy, and laboratories, emergency rooms, operating rooms, and rehabilitation and physical therapy rooms.

Some of the basic test instruments and tools needed by the maintenance facility include: volt-ohm meter, oscilloscope, tube tester, current leakage tester, pulse and function generators, precision power supply, temperature tester, defibrillator tester, cardiac equipment test set, isolation transformer circuit tester, electrosurgical analyzer, mercury vacuum tester for suction pumps, floor conductivity tester, electric outlet tester, other miscellaneous test equipment, and various hand and shop tools. 1/2/

The American Institute of Biological Sciences (AIBS) estimates that an internal equipment maintenance program for a hospital of about 100 beds and approximately 80 pieces of medical equipment generally requires one full-time technician. Half of his time will be spent in installing, checking, calibrating, and repairing equipment, and the other half in training equipment operators, compiling maintenance records, maintaining spare parts inventory, and up-dating his own competence. Larger hospitals will, of course, require a larger staff commensurate with the equipment to be maintained and the balance between internal and contracted maintenance services.

Equipment Maintenance Records

Accurate and complete records of all maintenance and repairs performed are particularly important to provide data for program evaluation and modification, cost analysis, equipment evaluation, and normal, preventive maintenance scheduling.

1/ Elements of An Instrumentation Repair Shop, Hospitals, May 1, 1975, Vol. 49, p. 55.

2/ Planned Preventive Maintenance and Electrical Safety Testing, Medical Electronics and Equipment News, August 1974, p. 9.

When available, the use of a computer for the maintenance program data system facilitates establishing a complete servicing record for medical equipment. Periodic computer printouts can be used to identify items that require inspection or preventive maintenance, items on which guarantees are expiring, items covered by maintenance contracts requiring service and monthly and cumulative preventive maintenance costs. The maintenance information system could easily be incorporated into the main computer systems used increasingly by the larger hospitals, and there are small, relatively inexpensive computer systems available that make their use feasible for almost any size hospital.

In implementing the system, the tasks to be accomplished should first be outlined in detail so that information requirements can be determined, compiled and entered into the data base. Some of the tasks and information requirements to be considered for a maintenance system are as follows:

Tasks

- 1) scheduling frequency and scope of all equipment maintenance to be performed, and
- 2) determining the most effective and economical level of spare parts inventory.

Information Requirements

- 1) coding system for identifying each item of equipment by type, model, maker, cost, location, etc.;
- 2) recording and storing equipment specifications and manufacturers' recommended maintenance procedures;
- 3) recording any equipment modifications that are made; and
- 4) scheduling and storing results of routine inspection, maintenance, and emergency repairs and for use in equipment evaluation and replacement determinations.

Appropriate forms should be designed and used for recording routine servicing of equipment, as well as emergency servicing; and the information should be entered in the data system to update the record on the item. This information file can also be useful to the hospital administrator in providing up-to-date information on the physical condition of medical equipment for comparison with depreciation schedules.

Spare Parts Inventory

Optimum operation of equipment demands prompt repair which makes a spare parts inventory essential. Because of the specialized nature of medical equipment, shortages of certain critical materials and rising costs, the planning of an inventory of spare parts requires careful consideration. The spare parts inventory should be modified as experience accrues.

Operational Details

A pre-acceptance inspection of equipment should be carried out by the ultimate user and appropriate professional interests to determine that: the item received is the model that was ordered and proper billing has been made; the item is complete and all accompanying components, accessories, manufacturer's technical data, schematics, and operation and service instructions are included; and the item is free from external and internal damage resulting from improper handling during shipment or faulty manufacturing.

Proper conduct of routine preventive maintenance is essential to the success of the program. On a service call the maintenance technician should review care and operation of the equipment with the operator and examine the equipment for any unreported problems. Routine maintenance includes cleaning and lubricating parts not readily accessible; calibrating the equipment; and performing operational tests for normal output or response. Equipment designated as life saving or life supporting should be carefully monitored in critical safety areas such as current leakage, grounding, serviceable condition of X-ray cables, etc., and compliance with state and federal safety standards.

Equipment calibration at manufacturer's stated intervals is required to assure uniformity and specified outputs. A brief certification form should be designed and attached to the item.

Certain equipment requires special calibration. , For example, X-ray therapy equipment which should be calibrated only by persons certified by the American Board of Radiology, and audiometers should be calibrated by a competent technician in accordance with International Standard Organizations (ISO) Standards.

Limits For Repair Costs

It is very important to determine the point at which an item of equipment should be replaced rather than repaired. Financial considerations obviously play an important role in this determination, but reliability of life-sustaining equipment is essential. The life expectancy for most electrical and electronic equipment is approximately 5 to 10 years, and 10 to 15 years for electromechanical equipment.

The life expectancy and depreciation rate of each item of equipment should be estimated by the medical maintenance staff depending upon frequency of use and environment.

When the cost of needed repairs exceeds the depreciated value of the equipment, consideration should be given to replacement. The decision whether or not to repair should consider expected serviceability after repair, urgency of local need, degree of obsolescence, and replacement cost.

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APPENDIX A

MEDICAL EQUIPMENT MAINTENANCE DATA

(Based on a query of hospital equipment specialists conducted by the American Hospital Association in 1972)

- A. Thirty-three equipment specialists responded to the questionnaire. Out of this total, 30 were from general hospitals, 2 were from medical schools, and 1 was from a hospital-clinic-nursing home.

1. The number of hospitals of different sizes (based on number of beds) that participated in the survey was as follows:

<u>Number of Beds</u>	<u>No. of Participants in Category</u>
1 up to 300	8
300 up to 500	8
500 up to 800	9
800 and over	8
Total	<u>33</u>

- B. The participants listed as their occupation, or as part of their title, the following:

	<u>No. of Participants</u>
Hospital Engineers	22
Hospital Maintenance	3
Hospital Plant Operation	6
Others	<u>2</u>
Total	<u>33</u>

- C. The participants' views on equipment maintenance were as follows:

1. Medical equipment maintenance represented a problem to 30 of the respondents.
 - a. Five indicated maintenance was a serious problem.
 - b. Eleven indicated that it was a substantial problem.
 - c. Fourteen indicated that it was a slight problem.
2. Medical equipment maintenance represented no problem to 3 of the respondents.

3. The significance of the maintenance problem increased with hospital size.
 - a. Based on 8 hospitals of 800 or more beds, 5 of the participants claimed maintenance was a serious problem, and 3, a substantial problem.
 - b. Based on 9 hospitals of 500 up to 800 beds,
 1. Five of the participants claimed maintenance was a substantial problem;
 2. Two of the participants claimed it was a slight problem;
 3. Two of the participants claimed it was not a problem.
 - c. Based on 8 hospitals of 300 up to 500 beds,
 1. Four of the participants claimed it was a slight problem;
 2. Four of the participants claimed it was a substantial problem.
 - d. Based on 8 hospitals of 1 up to 300 beds,
 1. Six of the participants claimed maintenance to be a slight problem;
 2. One of the participants claimed maintenance was not a problem;
 3. One of the participants did not answer the question.
- D. In response to the question concerning types of equipment used most frequently, there were 52 different types of equipment mentioned (Appendix B).

Out of the total number of equipment mentioned (156 counting repeats), the following is a percentage frequency distribution for the general types of equipment.

	<u>No. of Times Mentioned</u>	<u>% of Times Mentioned</u>
Diagnostic Equipment	57	36.6
Therapeutic Equipment	42	26.9
Laboratory & Other Equipment	32	20.5
Monitoring Equipment	25	16.0
Total	<u>156</u>	<u>100.0</u>

E. The breakdown on types of equipment stated to frequently need repair are as follows:

	<u>No. of Times Mentioned</u>	<u>% of Times Mentioned</u>
<u>Monitoring Equipment</u>	<u>15</u>	<u>29.4</u>
Cardiac	6	11.8
Patient	9	17.6
<u>Diagnostic Equipment</u>	<u>23</u>	<u>45.2</u>
ECG	10	19.7
X-Ray Units	9	17.7
Others	4	7.8
<u>Therapeutic Equipment</u>	<u>9</u>	<u>17.6</u>
Hemodialysis Machines	4	7.8
Defibrillators	2	3.9
Others	3	5.9
<u>Laboratory & Other Equipment</u>	<u>4</u>	<u>7.8</u>
Sterilizers	3	5.9
Others	1	1.9
Total	51	100.0

- F. Data supplied by the participants indicated that hospital equipment maintenance was conducted solely by an internal staff in 9 of 33 hospitals. In 3 cases, external services were used exclusively. The predominant preference was for a combination of internal and external services. The larger hospitals showed a tendency to rely more heavily on internal maintenance.

MAINTENANCE PERFORMERS

Maintenance Performed by:	Hospital Size		(Number of Beds)		Total	%
	1-300	300-500	500-800	800 up		
Internal Only	2	2	2	3	9	27
External Only		3			3	9
Combination	6	3	7	5	21	64
Totals	8	8	9	8	31	100

- G. Seventy-nine percent of participants stated that they had an inventory of spare parts for some pieces of equipment. The importance of the inventory increased with hospital size as depicted in the following table.

<u>HOSPITAL SIZE</u> (No. of Beds)	<u>NUMBER OF HOSPITALS WITH</u> <u>SPARE PARTS INVENTORY</u>	<u>% OF HOSPITALS WITH</u> <u>SPARE PARTS INVENTORY</u>
0 up to 300	4 out of 8	50.0
300 up to 500	5 out of 8	62.5
500 up to 800	9 out of 9	100.0
800 and Over	8 out of 8	100.0
	<u>26</u> <u>33</u>	<u>78.8</u>

- H. Spare parts inventories were mentioned most frequently for the following instruments:

<u>EQUIPMENT</u>	<u>NUMBER OF TIMES</u> <u>EQUIPMENT MENTIONED</u>	<u>% OF TIMES</u> <u>EQUIPMENT MENTIONED</u>
Cardiac Monitors	9	17.0
ECG	8	15.1
X-Ray Units	6	11.3
Defibrillators	3	5.7
Electro-surgical Equipment	3	5.7
Laboratory Equipment	3	5.7
Sterilizers	3	5.7
EEG	2	3.7
Others	<u>16</u>	<u>30.1</u>
	53	100.0

- I. Out of 30 responses to the question of whether parts inventory in the hospital was deemed critical, 18 of the participants stated that it was not, and 12 said that it was critical. The breakdown according to hospital size is as follows:

<u>HOSPITAL SIZE</u> (No. of Beds)	<u>NUMBER OF</u> <u>RESPONSES</u>	<u>"NO" RESPONSES</u>	<u>"YES" RESPONSES</u>
1 to 300	6	5	1
300 to 500	7	5	2
500 to 800	9	6	3
800 and Over	8	2	6
	<u>30</u>	<u>18</u>	<u>12</u>

- J. Thirty-one respondents answered the question whether the present warranties offered by companies were satisfactory. Fifteen of the respondents stated that they were; 14 of the respondents stated that they were not; and 2 stated that it would depend on the equipment.

The reasons most commonly given for dissatisfaction with warranty policies are as follows:

<u>REASONS</u>	<u>NUMBER OF TIMES</u> <u>MENTIONED</u>	<u>PERCENTAGE OF TIMES</u> <u>MENTIONED</u>
Limited Time & Parts Coverage	7	50.0
Poor Workmanship & Inadequate Servicing Personnel	4	28.6
Lengthy Repair Time	3	21.4
	<u>14</u>	<u>100.0</u>

- K. There were 33 responses to the question of whether warranties should continue to be offered. Twenty-seven of the respondents stated that they should, while 6 stated that it would depend on the type of equipment.

APPENDIX B

Most Frequently Used Medical Equipment in Hospitals

(As indicated by the hospital equipment specialists
queried by the American Hospital Association in 1972)

Diagnostic Equipment

Electrocardiographs (ECG)
Electroencephalographs (EEG)
X-Ray Units
Automated Blood Analyzers
Telemetry Equipment
Electromyographs (EMG)
X-Ray Processors
Hematology Equipment
Gas Chromatographs
Oscilloscopes
Recorders

Therapeutic Equipment

Defibrillators
Electro-surgical Equipment
Respiratory Care Equipment
Hemodialysis Machines
Pacemakers
Heart-Lung Machines
Heart Catheters
Resuscitators
Respirators
Nebulizers
Inhalation Therapy Equipment
Cautery Equipment
Diathermy Equipment
Physical Therapy Equipment
Heating Pads
Nuclear Therapeutic Equipment

Laboratory Equipment

Sterilizers
Centrifuges
Ultrasonic Cleaners
Autoclaves
Sanitizers
Glass Washers
Demineralizers
Distillation Equipment
Blood Gas Apparatus

Monitoring Equipment

Patient Monitors
Cardiac Monitors
Fetal Monitors

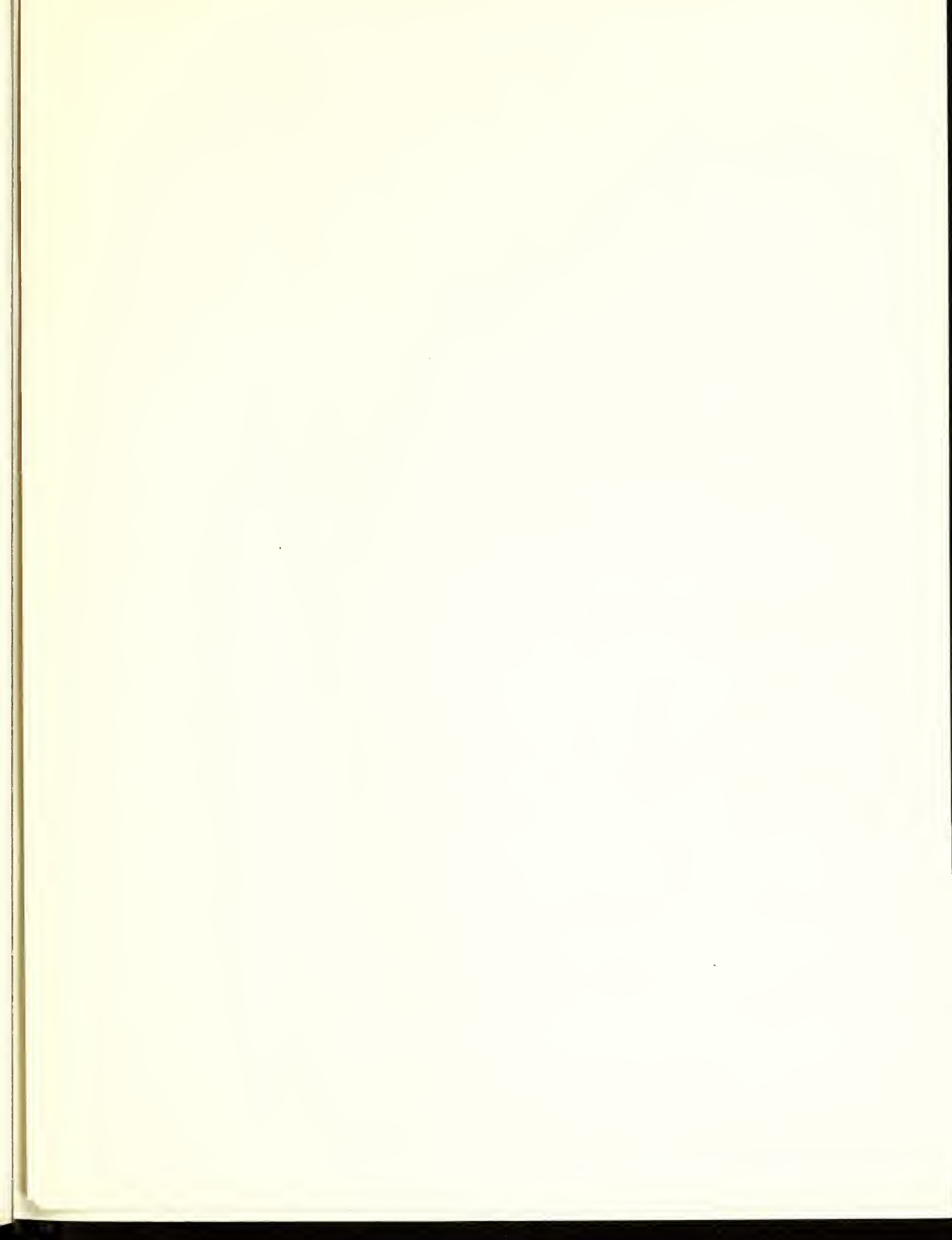
Other Equipment

Operating Room Equipment
Dental Equipment
Gomco Pump
Patient Nurse Call Equipment
Xerogram
Audiovisual equipment

APPENDIX C

Listing of Manufacturers of Patient Monitoring
Equipment and their Services

(Reprinted with permission of Medical Electronic
and Equipment News, February 1973,
Chilton Publications, Radnor, Pa.)



PATIENT MONITORING EQUIPMENT—1973 UPDATE

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